K063327

## 510k Summary of Safety and Effectiveness

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|---|---|
| **Date of Submission** | 1st June 2006. |
| **Submitter Name and Address** | Meridian Technique Ltd<br>2 Venture Road<br>Chilworth Science Park<br>Southampton<br>Hampshire<br>SO16 7NP<br>Great Britain |
| **Telephone**<br>**Fax** | 011 44 2380 762 500<br>011 44 2380 762 550 |
| **Official Correspondent Name and Address** | Mr Anthony Thorne<br>Omsbar Ltd<br>Unit 7 Building T2<br>Area 200<br>Milton Park<br>Abingdon<br>OX14 4TA<br>Great Britain |
| **Telephone**<br>**Fax** | 011 44 1235 820 401<br>011 44 1235 820 401 |
| **Classification and Name** | Class II – Picture Archiving and Communications (PACS) System |
| **Common Name** | PACS System |
| **Proprietary Name** | Orthoview™ |
| **Predicate Device** | 510k references K042816 and K032401 |

NOV 2 2 2006

Substantial equivalence is claimed between Orthoview™ and :

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|---|---|
| Manufacturer | Orthocrat Ltd |
| Tradename | TraumaCAD |
| Manufacturer | Meridian Technique Ltd |
| Tradename | Orthoview™ |

**Device Description –**

Orthoview™ is intended to provide the following functions for the Operator (a suitably qualified and trained healthcare professional):

- To be downloaded from the Internet and to be unlocked using a Meridian Technique Ltd provided key.
- Grant access rights only to authorized users (via PC password system).
- Receive X-Ray images in a digital format from third party X-Ray machines/ X-Ray digitisers or PACS systems.
- Process such images securely with respect to patient confidentiality, patient identification and image integrity.
- Allow the image to be retrieved for processing as follows:
    - Scaling of the image.
    - Selection of appropriate prosthetic and fixing device manufacturer and size range templates.
    - Overlaying the template on the image and permitting selection of appropriate size of prosthetic/fixing.
    - Provide additional functionality in the form of Trauma and Osteotomy modules
    - Print and archive appropriate reports.
    - Receive and store templates for prostheses and fixations supplied by Meridian Technique Ltd for particular manufacturer's range of products.
    - Provide traceability of operator, date and decisions made.

**Intended Use –**

Orthoview™ intended use is to enable a suitably licensed and qualified healthcare professional access to medical images with the intention of using such images, in conjunction with templates for prosthetic and fixation devices, for the purposes of choosing the nature and characteristics of the prosthetic/fixation device to be used when planning a potential surgical procedure. In addition, Trauma and Osteotomy modules and Trauma Templates are included to extend the range of functionality available to the healthcare professional.

**Assessment of Clinical and Non-clinical Performance Data**

Risk analysis indicates that Orthoview™ is identical to the predicate device in the patient environment. Orthoview™ uses similar materials and constructional principles to the predicate device. Due to this similarity, clinical testing of Orthoview ™ is considered unnecessary.

Orthoview ™ processes data in the form of Images collected in the patient environment after the event of actual collection. This non-patient contact processing is described exactly in terms of its software functions and associated Wizards and Templates. It is therefore feasible to verify and validate the functionality of Orthoview ™ outside of the clinical environment. This is the method which has been adopted.

**Conclusions of the Non-clinical Tests**

Verification and Validation of Orthoview ™ indicates that the requirements for intended use and associated performance characteristics are satisfied. In particular, the following functions have been tested and confirmed as operating according to specified requirements.

- Patient and Procedure Selection
- Image Scaling
- Procedure Planning
- Templating and Trauma (Fracture) reduction
- Osteotomy and alleviation of congenital deformity
- Committing and Saving operating session Data
- Compilation and Printing of associated Reports

| Comparison of Technological Characteristics | | |
|---|---|---|
| Characteristic | Orthoview™ | Predicate Devices |
| Computer | Personal Computer or Workstation/Server | Same |
| Availability of Device | Is used for planning orthopedic procedures using templates and wizards in the areas of Prosthetic placement, Trauma and Osteotomy | Same |
| Means of collecting data | Obtained from pre-obtained digital images via PACS system | Same |
| Processing of data | The software processes data to provide prosthetic and fixing template, trauma and osteotomy overlay and placement | Same |
| Patient Contact | No intentional patient contact | Same |
| Control of Life Sustaining Devices | None | Same. |
| Human intervention for interpretation | Requires physician intervention. | Same. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Merdian Technique, Ltd.
% Mr. Neil E. Devine, Jr.
Responsible Third Party Official
Intertek Testing Services NA, Inc.
2307 East Aurora Rd., Unit B7
TWINSBURG OH 44087

NOV 2 2 2006

Re: K063327
Trade/Device Name: Orthoview™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 2, 2006
Received: November 3, 2006

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology | 240-276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 894.xxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K063327

Device Name:

## Orthoview™

Orthoview™ is indicated for use when a suitably licensed and qualified healthcare professional requires access to medical images with the intention of using such images, in conjunction with templates for prosthetic and fixation devices, for the purposes of choosing the nature and characteristics of the prosthetic/fixation device to be used when planning a potential surgical procedure. In addition, Trauma and Osteotomy modules and Trauma Templates are provided to extend the range of functionality available to the healthcare professional.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)
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Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
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